Report of Opinions of James L. Gray, III, PharmD, MBA

## QUALIFICATIONS

I earned a Bachelor of Science in Pharmacy from the University of Pittsburgh and a Pharm. D. from Duquesne University. I completed my American Society of Health System Pharmacists ("ASHP") accredited residency at Mercy Hospital in Pittsburgh, Pennsylvania.

I am the Executive Director of Pharmacy at Barnes-Jewish Hospital in St. Louis, Missouri and have served in the pharmacy leadership position since 1983. I was a member of the Missouri Board of Pharmacy from 1997 through 2002 and served as its President from 2001 until 2002.

I have been continuously licensed as a pharmacist in the State of Missouri from 1983 until the present.

I am familiar with the recognized standards of acceptable professional practice applicable to the practice of pharmacy in St. Louis, Missouri during the relevant time periods, including throughout 2011 and 2012. Additionally, I am familiar with the recognized standards of acceptable professional practice for the operation of a health system pharmacy in St. Louis, Missouri during the period 2011 and 2012. Such knowledge includes the appropriate standard of care for procuring drugs for use in patients and the oversight and supervision of different operating entities of a health system such as Barnes-Jewish Hospital.

In my opinion, St. Louis and Nashville are similar communities.

More details regarding my education and training, as well as a list of my publications is contained in my *curriculum vitae*, copy attached. I have not testified as an expert witness during the past four years.

## INFORMATION REVIEWED

My statements are based on my background, training and experience as well as the following information, which I reviewed:

- Documents regarding the regulatory history of New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Center ("NECC");
- Information from the United States Centers for Disease Control and Prevention ("CDC"), including the *Morbidity and Mortality Weekly Report* dated December 13, 2002 regarding certain cases of fungal meningitis caused by contaminated epidural steroids made by a compounding pharmacy;
- Information from a October 23, 2003 hearing before the United States Senate's Committee on Health, Education, Labor, and Pensions regarding pharmacy compounding;

- Information published by the United States Food and Drug Administration ("FDA") regarding compounded drug products, compounding pharmacies, and the risks associated with compounded drugs;

- Information published by The American Society of Health System Pharmacists warning the pharmacy and medical community of the risks of using compounded drugs;

- Certain federal, Tennessee and Massachusetts pharmacy laws governing pharmacy compounding; and

- The depositions of Debra Schamberg, R.N., John Culclasure, M.D., Jeff Ebel, Carmen Leffler, D.Ph., Martin Kelvas, D.Ph., and Terry Grinder, D.Ph., all with exhibits, as well as portions of the deposition of Michael Schatzlein, M.D.

- United States Pharmacopeia (USP) (2008) Chapters 795 & 797 which establish national standards for non-sterile and sterile drug compounding respectively.

## SUMMARY OF FACTS

The substance of the facts and opinions are developed through my review of pertinent documents and deposition testimony taken in this case. In addition, I am relying on my education, training and experience including where applicable pertinent and relevant literature.

Dangers associated with Compounded Drugs

Traditional pharmacy compounding is defined as a process where a pharmacist combines, mixes, or alters ingredients to produce a medication that is custom made to meet a specific medical need based on an individual physician prescription for a specific patient. However, over the 30 years leading up to the NECC disaster (2012) some compounding pharmacies morphed into "non-traditional" pharmacy compounders. Specifically, these pharmacies engaged in production and shipment of large volumes of compounded drugs across state lines, compounded drugs that are essentially copies of FDA-approved commercially available drugs, compounded drugs outside of a pharmacist-patient-physician relationship without an individual patient prescription, and, finally, provided compounded drugs to third parties for sale, such as hospitals, clinics, physician offices, and home health providers. In effect, these compounding pharmacies operated like manufacturers while hiding under the mantel of state board of pharmacy regulation. In this way they avoided extensive federal regulations (cGMP -21 CFR Parts 210 and 211 enforced by the FDA) designed to insure a supply of safe and effective medications. For example, NECC was one such non-traditional compounding pharmacy operating under state board of pharmacy licensure while compounding slightly modified copies of FDA approved and regulated commercial products (such as methylprednisolone acetate- MPA) from non-sterile bulk chemicals (USP 797 high risk compounding). NECC then shipped large bulk quantities of these high risk products across state lines without required individual patient prescriptions, for use in epidural steroid injections. NECC offered lower prices than the commercially manufactured FDA approved products while they touted that their version of the steroids were preservative free, unlike the FDA approved version of the drugs. However, these compounded drugs were not

produced under strict FDA cGMP requirements. Thus, the precise formulation and sterile integrity of these drugs were undocumented. Neither non-traditional nor traditional compounding pharmacies are subject to the same FDA regulations as are FDA licensed manufacturers and compounded drugs are not FDA approved.

As non-traditional compounding emerged in the years preceding 2012 so also did reports of negative health events, some with horrific outcomes, after patients were administered compounded drugs prepared by compounding pharmacies. In fact, the serious risks of non-traditional pharmacy compounding were the subject of extensive public discussion in the pharmacy, medical, state and federal regulatory communities in the years leading up to 2012.

Trade groups joined public health officials warning of the special risks posed by these non-traditional compounded drugs. For example, in 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The CDC concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that...follows appropriate measures to ensure that injectable products are free of contamination."

In 2001, Kansas City, Missouri compounding pharmacist, Robert Courtney, was convicted for dispensing adulterated (diluted) doses of compounded IV chemotherapy. Courtney admitted supplying an estimated 98,000 adulterated doses to more than 4,200 cancer patients over the preceding 11 years, providing only a fraction of the prescribed dose to each patient. Profit was identified as Courtney's motivation. That wrongful conduct went undetected for 11 years because medical observation alone was not sufficient to detect the dilution scheme. In response to the Courtney case, as well as other identified cases of the distribution of adulterated and misbranded sterile products by compounding pharmacies, the Missouri State Board of Pharmacy initiated a routine sampling and testing program for compounded drugs. That program revealed failure rates of approximately 20% for the years 2006-2009, with individual findings ranging from 0% to 450% of labeled potency.

In 2003, roughly 1.4 million doses of compounded respiratory solution contaminated with *Burkholderia cepacia* were distributed to patients nationally. The Missouri State Board of Pharmacy found the pharmacy did not adequately recall potentially affected product and failed to advise patients and prescribers of the contamination risk. The Board issued a temporary restraining order, noting in their petition that the pharmacy "engaged in practices that pose a threat of immediate and irreparable injury, loss or damage to patients and presents a probability of serious danger to the health, safety or welfare of the residents of the state."

In October 2003, the United States Senate held a hearing regarding regulatory issues in the compounding industry. Experts testified at length regarding the dangers of compounded drugs during that hearing.

On March 24, 2005, *USA Today* published a front page article with the following headline: "**Safety concerns grow over pharmacy-mixed drugs**". That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

In 2006 the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the US during unannounced visits. Twelve (12) of the thirty-six (36) samples (33%) failed analytical testing for either potency or sterility. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

The American Society of Health System Pharmacists has also played an active role in warning the pharmacy and medical community of the risks of using compounded drugs. In 2010 they published the "ASHP Guidelines on Outsourcing Sterile Compounding Services." ASHP also developed a "Contractor Assessment Tool" for healthcare organizations to use in conjunction with their guidelines. That document was developed to be used by health systems when deciding whether and from where they should purchase compounded medications.

The foregoing is not an exhaustive list of publicly available information regarding the risks associated with compounded drugs; rather it is a representative sample of the types of information available.

NECC History

NECC operated a non-traditional compounding pharmacy in Framingham, Massachusetts. Before the meningitis catastrophe that became widely recognized in the fall of 2012, NECC had a history of adverse events relating to its operations. Of note, NECC operated its purportedly sterile compounding pharmacy on a site shared with a garbage compacting and mattress recycling business.

NECC was the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP"). Those complaints and investigations often focused on unsterile conditions at NECC's facilities. For example, in 2002 five patients became ill after receiving epidural injections of bacteria tainted MPA compounded and distributed by NECC. One of these patients died from complications of bacterial meningitis. A subsequent inspection by the FDA and the MBP identified numerous process and procedural problems at the NECC facility. In 2006 the FDA issued a Warning Letter to NECC. The FDA letter details additional violations at NECC including the sale of compounded drugs without patient-specific prescriptions. Further, the FDA's Warning Letter stated that NECC was compounding copies of commercially available drugs, selling misbranded compounded drugs, and experiencing problems with storage and sterility. That warning letter was available on the FDA's website 6 years before NECC distributed nearly 20,000 doses of fungus contaminated methylprednisolone acetate for use in epidural steroid injection for the symptomatic relief of back pain.

Compounded Drugs Require Individual Prescriptions

The preparation, sale and distribution of compounded drugs, in bulk and without individual prescriptions, is unlawful in Tennessee and Massachusetts. In order for drugs to be procured from a compounding pharmacy, patient-specific prescriptions involving the prescriber-patient-pharmacist relationship must be used. *See T.C.A. § 63-10-204(4); Mass. Gen. Law c. 94C, § 17(c); and 21 U.S.C. § 353a.* See, also, deposition of Terry Grinder, D.Ph.

Saint Thomas Outpatient Neurosurgical Center

Saint Thomas Outpatient Neurosurgical Center ("Saint Thomas Neurosurgical") is a facility located in Nashville, Tennessee. Although it is licensed as an ambulatory surgery center, per testimony, no neurosurgeons actually work there and no surgeries are performed there. Saint Thomas Neurosurgical specializes in providing epidural steroid injections for the symptomatic relief of spine pain to patients of a neurosurgery group known as the Howell Allen Clinic.

According to Michael Schatzlein, M.D., President and CEO of Saint Thomas Health, Saint Thomas Neurosurgical is a for profit joint venture which is part of the Saint Thomas Health system. Saint Thomas Neurosurgical is owned jointly by Saint Thomas Network and Howell Allen Clinic. Saint Thomas Network and Howell Allen Clinic share the profits generated by Saint Thomas Neurosurgical equally. Saint Thomas Network is wholly owned by Saint Thomas Health. Dr. Schatzlein described Saint Thomas Network as a pass through entity with zero employees.

According to its website, the Saint Thomas Health System is a family of Middle Tennessee hospitals and physician practices. The hospitals include: Saint Thomas West Hospital in Nashville (formerly Saint Thomas Hospital), Saint Thomas Midtown Hospital in Nashville (formerly Baptist Hospital), Saint Thomas Hospital for Specialty Surgery in Nashville, and Saint Thomas Rutherford Hospital in Murfreesboro (formerly Middle Tennessee Medical Center).

Saint Thomas Neurosurgical is located on the 9th floor of the Medical Plaza East on the Saint Thomas Hospital/Saint Thomas West campus. Saint Thomas Neurosurgical's receptionist, Sheri DeZwaan, wore a name tag bearing the name "Saint Thomas Hospital" at the top. In addition, Dr. Schatzlein testified as follows:

> Q. Do you -- would it surprise you to learn that patients who went to the St. Thomas Outpatient Neurosurgical Center believed that they were receiving care from an entity that was part of the St. Thomas Health system?
>
> A. I guess I'd have to say, no, it wouldn't surprise me.

Saint Thomas Neurosurgical conducted a high volume epidural steroid injection practice. In 2011 and 2012, Saint Thomas Neurosurgical performed an average of 450 to 500 epidural steroid injections each month. It performed roughly 5,000 epidural steroid injections each year.

The Medical Director of Saint Thomas Neurosurgical does not receive a salary. He is paid a percentage of collections for the epidural injections that he gives. Specifically, Dr.

Culclasure is paid an amount equal to sixty percent (60%) of the collections for each shot that he gives.

Saint Thomas Hospital Declines to Purchase from NECC

According to Martin Kelvas D.Ph., former Director of Pharmacy Services for Saint Thomas Hospital, he specifically instructed all pharmacy staff on the non-profit side of the Saint Thomas Health System not to purchase drugs from compounding pharmacies. Dr. Kelvas testified that, in early 2011, a sales representative from NECC approached Dr. Kelvas in order to solicit Saint Thomas Hospital's business. NECC proposed selling compounded medications in bulk to the hospital. Based upon Dr. Kelvas' general knowledge of pharmacy laws, he did not feel that the proposed arrangement was lawful. Accordingly, he declined NECC's solicitation, and he called the Tennessee Board of Pharmacy.

Dr. Kelvas then talked with Terry Grinder, D.Ph. of the Tennessee Board of Pharmacy. Dr. Grinder affirmed Dr. Kelvas' interpretation of Tennessee and federal law. Compounded drugs could not be legally purchased from a compounding pharmacy in bulk. Compounded drugs may only be dispensed by a board of pharmacy licensed compounding pharmacy to fulfill a patient specific prescription written by a physician (i.e. within the prescriber-patient-pharmacist relationship). Dr. Grinder further explained that, in order to procure medications without individual prescriptions, the drugs must be procured from an entity with a manufacturer's license.

After confirming that NECC's solicitation was not legal, Dr. Kelvas instructed all pharmacy personnel on the non-profit side of the Saint Thomas Health system (i.e. Saint Thomas West Hospital in Nashville, Saint Thomas Midtown Hospital in Nashville, Saint Thomas Hospital for Specialty Surgery in Nashville and Saint Thomas Rutherford Hospital in Murfreesboro) not to purchase from compounding pharmacies. However, Saint Thomas Health leadership failed to instruct anyone on the for-profit side of its organization not to buy in bulk from compounding pharmacies.

Dr. Grinder of the Tennessee Board of Pharmacy testified that procuring medications, in bulk and without individual prescriptions, from compounding pharmacies was not lawful. Whenever healthcare providers called his office with questions about compounding pharmacies, Dr. Grinder explained that medications could only be procured from compounding pharmacies by using individual prescriptions based upon the prescriber-patient-pharmacist relationship. Bulk purchases without prescriptions could not be made from compounding pharmacies. Bulk purchases could only be made from entities with a wholesaler, manufacturer or distributor's license. NECC did not have such a license.

Saint Thomas Neurosurgical Purchases Injectable Steroids in Bulk from NECC

John Culclasure, M.D. is Saint Thomas Neurosurgical's Medical Director. Debra Schamberg, R.N. is the clinic's Facilities Director. Ms. Schamberg has no pharmacy training. Per testimony, Dr. Culclasure and Ms. Schamberg jointly made the decision for Saint Thomas Neurosurgical to make bulk purchases of methylprednisolone acetate ("MPA") from NECC without individual patient prescriptions.

In late 2010, Saint Thomas Neurosurgical purchased MPA from a properly licensed supplier in Nashville, Tennessee known as Clint Pharmaceuticals. The MPA that Saint Thomas Neurosurgical bought from Clint Pharmaceuticals did not come from a compounding pharmacy. Clint Pharmaceuticals only supplied steroids manufactured by FDA regulated pharmaceutical companies. All of the MPA purchased by Saint Thomas Neurosurgical from Clint Pharmaceuticals was FDA approved and all contained preservatives.

In June of 2011, Saint Thomas Neurosurgical chose to stop buying FDA approved steroids through Clint Pharmaceuticals and start buying compounded MPA from NECC. Saint Thomas Neurosurgical made that change when Clint Pharmaceuticals increased its price for FDA approved generic MPA from $6.49 per vial to $8.95 per vial. Emails sent and received by Ms. Schamberg establish that Saint Thomas Neurosurgical switched from purchasing FDA approved steroids to purchasing compounded steroids from NECC and thereby saved $2.46 per vial.

Dr. Culclasure and Ms. Schamberg both testified the decision to purchase from NECC was motivated by an impending shortage of MPA rather than the lower price of the NECC product. However, testimony by Clint Pharmaceuticals owner Jeffery Ebel confirmed that his firm had sufficient stock of the branded Depo-Medrol to supply all the needs of Saint Thomas Neurosurgical Center. Further, testimony by Dr. Culclasure and Ms. Schamberg that the NECC preservative free product was necessary vs. the preserved Depo-Medrol is contradicted by the Neurosurgical Center's previous use of the commercially prepared preserved products with no patient problems noted. Additionally, the vast majority of epidural steroid injections administered in the United States were then, and continue to be, performed using the preserved commercial MPA products… again with no reported patient adverse outcomes.

According to invoices produced by Saint Thomas Neurosurgical, the clinic purchased two thousand five hundred (2,500) vials of MPA from NECC during a period of three months during the summer of 2012. That volume made Saint Thomas Neurosurgical NECC's largest customer by volume for the purchase of MPA during the critical three month period when NECC distributed tainted pharmaceuticals throughout the country.

Per testimony by Dr. Culclasure and Ms. Schamberg, Saint Thomas Neurosurgical decided to purchase compounded MPA from NECC with no knowledge of Tennessee or federal laws regulating the sale of compounded drugs nor any effort to learn about sterile compounded medications in general or NECC in particular. For example, they did not:

- Understand the substantial difference between a compounding pharmacy and an FDA regulated manufacturer;
- Review publically available FDA and professional publications warning of the dangers of pharmacy compounded sterile drugs;
- Validate NECC's current licensure with Massachusetts, Tennessee or the FDA;
- Request copies of any state or federal inspection reports, regulatory sanctions or actions or any reports of patient injury or deaths related to administration of NECC's compounded sterile products;

- Request to review NECC's sterility testing results;
- Verify information contained in NECC's promotional literature; and
- Consult with a pharmacist for advice about purchasing non-FDA approved compounded drugs despite the fact they testified a consultant pharmacist was indeed available to them.

Noteworthy, Dr. Culclasure and Ms. Schamberg never even Googled NECC before they selected NECC to be Saint Thomas Neurosurgical's preferred supplier of injectable MPA.

Despite Dr. Culclasure and Ms. Schamberg's testimony that they carefully reviewed NECC's promotional literature before approving the purchase of MPA from NECC, they failed to heed the following statement:

**G. Dispensing**

> Product is dispensed by patient-specific prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or facility.

In spite of that statement, Saint Thomas Neurosurgical proceeded with bulk purchases of MPA from NECC (frequently in 500 vial batches) without using patient-specific prescriptions.

Saint Thomas Neurosurgical sends patient lists to NECC

In early to mid-2012, an NECC representative informed Saint Thomas Neurosurgical that NECC needed to receive lists of patients with each order for MPA. NECC made that request more than six months after Saint Thomas Neurosurgical started making bulk purchases from NECC. The NECC representative explained that NECC needed patient lists in order to comply with Massachusetts Board of Pharmacy requirements.

Ms. Schamberg (Saint Thomas Neurosurgical's Facilities Director) then told the NECC representative that she could not predict which patients would receive MPA. Therefore, Saint Thomas Neurosurgical could not provide lists that would actually correspond with patients who receive MPA. In response, the NECC representative indicated that any list of patient names would suffice.

After receiving that request, Saint Thomas Neurosurgical occasionally sent patient lists to NECC, although it did not send a list with each order. Saint Thomas Neurosurgical sent those lists even though the lists did not correspond with patients who actually received MPA compounded by NECC. Saint Thomas Neurosurgical sent those lists without regard to patient privacy provisions contained in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

Patients Contract Fungal Meningitis and Die

According to Dr. Culclasure, more than a hundred (100) patients contracted fungal meningitis after receiving contaminated epidural steroid injections at Saint Thomas Neurosurgical. Thirteen (13) patients died.

OPINIONS

I am prepared to offer the following opinions at the trial of this case:

Products from compounding pharmacies are inherently less safe and more risky than FDA approved drugs made by licensed pharmaceutical manufacturers. A June 3, 2013 report prepared for congress by the Congressional Research Service stated that 33% of compounded drugs sampled by the FDA in 2006 failed analytical testing, much higher than commercially prepared and FDA regulated drugs where only 2% failed testing. FDA regulated pharmaceutical manufacturers are required to follow strict manufacturing and quality control standards known as current Good Manufacturing Practices (cGMP – 21 CFR Parts 210 and 211). Those standards are much more stringent, and produce products that are much less likely to contain harmful contaminants or variations in content, than products made by compounding pharmacies. Compounding pharmacies are regulated by state boards of pharmacy and do not operate under the same degree of safety focused scrutiny. Defects in compounded drugs are primarily detected after the products are sold and administered to patients. The stringent pre-release testing required of FDA regulated manufacturers under cGMP insures production errors are less likely to occur. Further, when defects do occur, commercially manufactured drug defects are usually detected prior to distribution or patient administration.

The comparable risks of purchasing from a compounding pharmacy are significant as well as potentially lethal, as demonstrated in case histories from around the country.

NECC is a compounding pharmacy and could not lawfully sell compounded drugs except in response to an individual prescription based upon the prescriber-patient-pharmacist relationship. NECC could not sell compounded drugs in bulk.

During all relevant times, there were commercially available steroids for use in ESIs. Any purported shortage of steroids for use in ESIs is not factually accurate and in any event would be an insufficient reason to purchase bulk non-patient specific steroids for ESIs from a compounding pharmacy.

The Saint Thomas Health system failed to protect the safety of patients by failing to make sure that entities on the for-profit side of its organization followed the same rules and pharmacy procurement laws as those entities on the non-profit side of its organization. Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Neurosurgical, all as part of the Saint Thomas Health system, failed to take appropriate steps to insure that appropriately trained personnel were in place at Saint Thomas Neurosurgical to protect the safety of patients with regard to the procurement of steroids for use in ESIs. Further, despite the fact that the pharmacy director of Saint Thomas Hospital confirmed with the Tennessee Board of Pharmacy in early 2011 that NECC could not sell compounded drugs in Tennessee without a patient specific prescription AND communicated this information across the Saint Thomas Network, Saint Thomas Health leadership failed to notify personnel on the for-profit side of the system – Saint Thomas Neurosurgical - that purchasing compounded medications, in bulk and without individual prescriptions, was neither safe nor lawful.

Patients on the for-profit side of the Saint Thomas Health system, such as those of Saint Thomas Neurosurgical, deserve the same degree of care and safety in medication procurement as do patients on the non-profit side of the system. The failure by the Saint Thomas Health system

(including Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Neurosurgical) to make sure that medications were not purchased from compounding pharmacies, in bulk and without individual prescriptions, fell below the standard of care and was negligent and reckless.

It was a breach below the applicable standard of care for Saint Thomas Neurosurgical to purchase steroids from a compounding pharmacy. Unless a special medical need existed to administer compounded steroids to a particular patient (which it did not), it was a breach below the applicable standard of care to purchase steroids from a compounding pharmacy without patient specific prescriptions. It was a further breach below the applicable standard of care for Saint Thomas Neurosurgical to purchase compounded drugs in bulk from NECC.

Saint Thomas Neurosurgical could have purchased FDA approved Depo-Medrol manufactured by Pfizer for a slightly higher price or else it could have purchased another brand of corticosteroid from an FDA approved manufacturer. Saint Thomas Neurosurgical was negligent, reckless and fell below the standard of care in choosing to purchase compounded medications when FDA approved products were available.

Based on their deposition testimony, Dr. Culclasure and Ms. Schamberg did not have an appropriate understanding or appreciation of the risks inherent in purchasing from a compounding pharmacy. Untrained employees, without any knowledge of pharmaceutical rules and processes, should not be permitted to make such decisions on their own. Saint Thomas Neurosurgical knew or should have known that medications purchased from NECC could only be acquired and dispensed pursuant to individual patient-specific prescriptions. NECC's promotional literature stated as much. In addition, Saint Thomas Neurosurgical would have learned of the individual prescription requirement if it had contacted the Tennessee Board of Pharmacy, as did Dr. Kelvas. In fact, both Dr. Culclasure and Ms. Schamberg testified they knew, or knew of, Dr. Kelvas and could easily have contacted him for guidance. Saint Thomas Neurosurgical was negligent, reckless and fell below the standard of care by not knowing or learning about the rules applicable to pharmacy purchases nor reviewing publically available information outlining the risks associated with a compounding pharmacy in general or the regulatory history of NECC specifically.

Saint Thomas Neurosurgical, its agents and employees were negligent, reckless and fell below the standard of care when it ignored certain red flags regarding NECC's practices. Specifically, Saint Thomas Neurosurgical overlooked NECC's willingness to distribute prescription medications without prescriptions, and it went along with NECC's request for lists of random patient names. NECC's conduct should have alerted Saint Thomas Neurosurgical that NECC was not a trustworthy source for procuring purportedly sterile injectable steroids.

It is my opinion that the above described conduct resulted in or caused injuries that otherwise would not have occurred.

I reserve the right to amend this disclosure in the event I receive additional pertinent information or, if necessary, to rebut any opinions offered by Defendants' experts.

COMPENSATION

I have been compensated in the amount of $15,930 by counsel for reviewing materials and authoring this report. My rate for testimony and reviewing this matter is $300 per hour.

James L. Gray, III, PharmD, MBA

10-9-2015
Date

Addendum to Report of Opinions of James L. Gray, III, PharmD, MBA

As stated in my Report of Opinions of October 9, 2015, I am familiar with the recognized standards of acceptable professional practice applicable to the practice of pharmacy in St. Louis, Missouri during the relevant time periods, including throughout 2011 and 2012. Additionally, I am familiar with the recognized standards of acceptable professional practice for the operation of a health system pharmacy in St. Louis, Missouri throughout 2011 and 2012. Such knowledge includes the appropriate standard of care for procuring drugs for use in patients and the oversight and supervision of different operating entities of a health system such as Barnes-Jewish Hospital.

Based on information provided to me relating to Nashville, Tennessee including but not limited to the number of hospitals, community size, availability of medical specialties and medical services, demographic information including population, median age, median income, gender and educational background, it is my opinion that St. Louis and Nashville are similar communities. It is my opinion that the standard of care for the oversight and supervision of drug procurement practices in a health system is the same in St. Louis, Nashville or other similar communities.

James L Gray III

James L. Gray, III, PharmD, MBA

12-10-2015

Date

# JAMES L. GRAY, III
# CURRICULUM VITAE

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## CURRENT LICENSURE:

Missouri, November 1983

## PROFESSIONAL EXPERIENCE:

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|---|---|
| September 2013 to present | Executive Director<br>Pharmacy<br>Barnes-Jewish Hospital<br>Washington University Medical Center<br>St. Louis, Missouri |
| May 1983 to September 2013 | Director of Pharmacy<br>Barnes-Jewish Hospital<br>Washington University Medical Center<br>St. Louis, Missouri |
| February 1997 to October 2002 | Member<br>Missouri Board of Pharmacy<br>(Board President July 2001 to September 2002) |
| October 1988 to October 1995 | Director of Transplant Services<br>Barnes-Jewish Hospital<br>Washington University Medical Center<br>St. Louis, Missouri |
| August 1980 to May 1983 | Associate Director of Pharmacy<br>Park Plaza Hospital<br>Lifemark Pharmacy Management, Inc.<br>1313 Hermann Drive<br>Houston, Texas |
| February 1979 to July 1980 | Assistant Director/Clinical Services<br>Pharmacy Department<br>Park Plaza Hospital<br>1313 Hermann Drive<br>Houston, Texas |
| July 1977 to January 1979 | Assistant Professor<br>Division of Pharmacy Practice<br>Ohio State University<br>College of Pharmacy<br>Columbus, Ohio |

## EDUCATION:

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|---|---|
| MBA | May 2001<br>John M. Olin School of Business<br>Washington University<br>St. Louis, Missouri |
| Doctor of Pharmacy | August 1977<br>Duquesne University<br>School of Pharmacy<br>Pittsburgh, Pennsylvania |
| ASHP Residency | May 1977<br>Mercy Hospital<br>Pittsburgh, Pennsylvania |
| B.S. in Pharmacy<br>(Summa cum Laude) | April 1975<br>University of Pittsburgh<br>School of Pharmacy<br>Pittsburgh, Pennsylvania |

## PROFESSIONAL ORGANIZATIONS:

American Society of Health System Pharmacists
St. Louis Society of Health System Pharmacists
Missouri Society of Health System Pharmacists
Missouri Pharmacists Association

## HONORS:

Rho Chi National Pharmacy Honorary Society (1974)
Beta Gamma Sigma Business Honorary Society (2001)
Class Speaker, Olin School of Business, Washington University (HSM III, 2001)

## AWARDS:

Missouri Society of Hospital Pharmacists
Research and Education Foundation
The Thomas J. Garrison Achievement Award- 1993

## RESEARCH:

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| TITLE: | Antibiotic Cost Savings and Standards of Usage |
| SUPPORT: | Funded by a grant from Barnes Hospital |
| CO-INVESTIGATORS: | RS Woodward, G Medoff, MD Smith, and JL Gray |

## PUBLICATIONS:

Gray JL: The effect of demeclocycline on free water clearance, Pharmacy Practice 12:41 (Jun) 1977

Flaska L and Gray JL: Converting from short- to long-acting antihypertensives (letter), Drug Therapy 7:8 (Aug) 1982

Gray JL, Evans G, Diener T, Tiemann M: OSHA regulations concerning cytotoxic agents (letter), Am J Hosp Pharm 41:630 1984

Woodward RS, Medoff GE, Smith MD and Gray JL: Antibiotic cost savings from formulary restrictions and physician monitoring in a medical school affiliated hospital, Am J Med 83:817-823, (Nov) 1987

Hancock DR, Beckner RR and Gray JL: Pharmacy participation in pharmaceutical representative displays in a large teaching hospital, Hosp Pharm 24:39-42, (Jan) 1989

Dunagan WC, Woodward RS, Medoff GE, Gray JL, Casabar E, Smith MD, Lawrenz CA, and Spitznagel E: Antimicrobial misuse in patients with positive blood cultures, Am J Med 87:253-259, (Sept) 1989

Dunagan WC, Woodward RS, Medoff G, Gray JL, Casabar E, Lawrenz CA, Spitznagel E, and Smith MD: Antimicrobial misuse in two clinical situations: positive blood culture and administration of aminoglycosides, Rev Infect Dis, 13:405-12, (May-June) 1991

## PRESENTATIONS:

Gray JL, Evans G, Diener T, Tiemann M: Impact of OSHA safety and health standards (29 CFR 1910) on IV additive rooms preparing cytotoxic agents, American Society of Hospital Pharmacists' Midyear Clinical Meeting, Dallas, Texas, December 6, 1984

Gray JL, Venker D, and Tiemann M: Justification and implementation of decentralized pharmacy services in the operating rooms of a private teaching hospital, American Society of Hospital Pharmacists' Midyear Clinical Meeting, New Orleans, Louisiana, December 9, 1985

Casabar E, Gray JL, Medoff GE, and Packman R: Mandatory antibiotic restrictions - the clinical pharmacist's role, American Society of Hospital Pharmacists' Midyear Clinical Meeting, Dallas, Texas, December 7, 1988

Casabar E, Gray JL, West M, and Medoff GE: A standardized system for general surgery prophylaxis at a large, private teaching hospital- a multi-disciplinary approach, American Society of Hospital Pharmacists' Midyear Clinical Meeting, Atlanta, Georgia, December, 1989

Garber V, Gray JL, Portwood R, Rackers A: Mobile Pharmacy- Prescription Bedside Delivery, UHC Annual Conference 2013, Atlanta, Georgia, October 17, 2013

## POSTER PRESENTATIONS:

Hancock D, Gray JL, Evans G, and Hancock R: Developing a vancomycin automatic stop order policy with restrictions for renewal - a descriptive report, American Society of Hospital Pharmacists' Annual Meeting, Reno, Nevada, June, 1985

Hancock D, Ballard R, and Gray JL: Quality and cost impact of decentralized pharmacy services to an outpatient

surgery center, American Society of Hospital Pharmacists' Midyear Clinical Meeting, New Orleans, Louisiana, December 10, 1985

Queenson G, Hancock D, Hailstone S, and Gray JL: Discharge medication teaching at a large private teaching hospital - a descriptive report, American Society of Hospital Pharmacists' Midyear Clinical Meeting, New Orleans, Louisiana, December 11, 1985

Losson M, Gray JL, and Hancock D: Microcomputer use at a large teaching hospital - a descriptive report, American Society of Hospital Pharmacists' Midyear Clinical Meeting, New Orleans, Louisiana, December 12, 1985

Ott M, Evans G, and Gray JL: Computer based perpetual inventory and scheduled auditing of controlled substances in a 1200 bed teaching hospital, American Society of Hospital Pharmacists' Midyear Clinical Meeting, Las Vegas, Nevada, December 8, 1986

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